IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MORTON GROVE PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	No. 08-CV-1384
vs.	)	Judge Bucklo Magistrate Judge Mason
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

DEFENDANT THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S ANSWER AND AFFIRMATIVE AND OTHER DEFENSES TO PLAINTIFF'S COMPLAINT, AND COUNTERCLAIM AGAINST MORTON GROVE PHARMACEUTICALS, INC.

Defendant, the National Pediculosis Association, Inc. ("NPA"), by and through its attorneys, Jenner & Block LLP, for its Answer and Affirmative and Other Defenses to Plaintiff's Complaint, and Counterclaim against Morton Grove Pharmaceuticals, Inc. ("Morton Grove"), states as follows:

Nature Of Action

1. This is an action brought to redress false, misleading and deceptive statements and comparative advertisements regarding two FDA-approved drugs—Lindane Lotion and Lindane Shampoo—prescribed for the treatment of lice and scabies.

ANSWER: NPA denies all allegations set forth in paragraph 1.

2. Plaintiff Morton Grove is a pharmaceutical company. Defendant NPA is the distributor of the LiceMeister® Comb, which competes with Lindane medications. While the NPA refers to itself as an "agency dedicated to protecting children from the misuse and abuse of potentially harmful lice and scabies pesticidal treatments" and masquerades as a health organization, upon information and belief, the NPA does not employ a single physician or licensed health professional. It is a competitor of Morton Grove. In fact, in 2003, 97% of the NPA's revenues were derived through the sale of LiceMeister® combs.

ANSWER: NPA is informed and believes, and therefore admits, that Morton Grove is a pharmaceutical company. Further, NPA admits that it is an agency dedicated to protecting children from the misuse and abuse of potentially harmful lice and scabies pesticide treatments, that it sells a medical device called the LiceMeister® Comb, and that it does not currently have on its payroll a physician or licensed health professional. NPA affirmatively avers that it has relied on and currently relies on the expertise of advisors who are licensed health care professionals. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 2.

3. Morton Grove brings this action against the NPA for violation of the Lanham Act, trade disparagement, and violation of the Illinois Deceptive Trade Practices Act.

ANSWER: NPA admits that Plaintiff has filed suit against it and attempted to state claims for violation of the Lanham Act, for trade disparagement, and for violation of the Illinois Deceptive Trade Practices Act. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 3.

4. Morton Grove is the only United States manufacturer and distributor of Lindane medications. As such, the NPA's statements regarding "lindane" necessarily refer to Morton Grove and its products.

ANSWER: NPA lacks sufficient information and knowledge to answer, and therefore denies, the allegation set forth in paragraph 4 that "Morton Grove is the only United States manufacturer and distributor of Lindane medications." The allegation set forth in paragraph 4 that "[a]s such, the NPA's statements regarding 'lindane' necessarily refer to Morton Grove and its products" is a legal conclusion to which no response is required. To the extent this legal conclusion can be construed as containing allegations of fact, NPA denies them.

5. Lindane medications have been approved by the Food and Drug Administration ("FDA") as [a] safe and effective prescription therapy for the treatment of lice and scabies. These infections, some of which are sexually transmitted, are increasingly resistant to certain treatments and remain important public health problems that affect tens of millions of Americans each year.

ANSWER: NPA admits that the FDA has approved lindane as a second-line prescription pesticidal treatment for lice and scabies, that scabies can be sexually transmitted, that lice and scabies are important health problems, and that some studies have suggested that lice and scabies may be resistant to certain treatments. NPA affirmatively avers that in 2003, the FDA issued a Public Health Advisory warning of the serious risks in using Lindane Lotion USP 1% ("Lindane Lotion") and Lindane Shampoo USP 1% ("Lindane Shampoo") for the treatment of scabies and lice. NPA further affirmatively avers that in 2003, the FDA mandated new labeling and packaging requirements for Lindane Lotion and Lindane Shampoo, including the addition of a "black box" public health warning that warns that lindane pesticidal treatments "should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications," that "[s]eizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application according to directions," and that lindane pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity." NPA further affirmatively avers that a "black box" warning or "boxed warning" represents a stringent labeling requirement and reflects serious concerns on the part of the FDA as to the dangers and risks presented by use of the drug. NPA lacks sufficient current information and knowledge to answer, and therefore denies, the allegation in paragraph 5 regarding the number of Americans affected each year by lice

and scabies. Except as expressly admitted herein, NPA denies all allegations in paragraph 5.

6. In the 50+ years that Lindane medications have been on the market, subject matter experts working with the FDA and the Environmental Protection Agency ("EPA") have reviewed the weight of medical and scientific evidence on Lindane medications and repeatedly determined that these medications are safe and effective when used as directed. The FDA has consistently maintained its position that the benefits of Lindane medications outweigh its risks—a factor for all medications—and should remain an option for physicians. Petitions, including one filed by the NPA, to ban Lindane medications have repeatedly been denied and determined to be without merit.

ANSWER: NPA admits that the FDA has stated that the benefits of lindane pesticidal treatments outweigh their risks only when used as directed and in accordance with FDA's guidelines, that NPA's petition to the FDA to ban pharmaceutical uses of lindane was denied, and that so far, the FDA has denied all petitions to ban pharmaceutical uses of lindane, though it has placed increasing restrictions on the use of these treatments. NPA affirmatively avers that in 2003, the FDA issued a Public Health Advisory warning of the serious risks in using Lindane Lotion and Lindane Shampoo for the treatment of scabies and lice. NPA further affirmatively avers that in conjunction with the issuance of the Public Health Advisory, the FDA mandated new labeling and packaging requirements for Lindane Lotion and Lindane Shampoo, including the addition of a "black box" public health warning that warns that lindane pesticidal treatments "should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications," that "[s]eizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application according to directions," and that lindane pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity."

NPA further affirmatively avers that a "black box" warning or "boxed warning" represents a stringent labeling requirement and reflects serious concerns on the part of the FDA as to the dangers and risks presented by use of the drug. NPA also affirmatively avers that the FDA mandated a "black box" warning for lindane pesticidal treatments "to better inform both healthcare professionals and patients regarding the potential risks associated with the use and misuse of Lindane" because "[g]iven the possible risks associated with the use of Lindane, healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug events." Except as expressly admitted herein, NPA denies all allegations in paragraph 6.

7. Similarly, the EPA has concluded that pharmaceutical Lindane poses no significant risk to humans or the environment when used as currently labeled.

ANSWER: NPA denies all allegations set forth in paragraph 7.

8. The public health benefits of Lindane medications are further supported by the recommendations of the Centers for Disease Control and Prevention ("CDC"). The CDC sets practice standards for the medical community and includes Lindane medications in its Sexually Transmitted Disease Treatment Guidelines for the management of scabies and pubic lice, consistent with the FDA-approved prescription labeling for Lindane Lotion and Lindane Shampoo.

ANSWER: NPA admits that the CDC publishes treatment guidelines for the medical community and that lindane pesticidal treatments are mentioned in the CDC's 2006 *Sexually Transmitted Disease Treatment Guidelines* as available treatments for scabies and pubic lice. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 8.

9. Moreover, in 2003, important advancements to the packaging and prescription of Lindane medications manufactured and sold in the United States served to mitigate the potential risks associated with product misuse and further enhanced their public safety.

ANSWER: NPA admits that in 2003, the FDA mandated new labeling and packaging requirements for Lindane Lotion and Lindane Shampoo, including the addition of a "black box" public health warning that warns that lindane pesticidal treatments "should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications," that "[s]eizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application according to directions," and that lindane pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity." NPA affirmatively avers that a "black box" warning or "boxed warning" represents a stringent labeling requirement and reflects serious concerns on the part of the FDA as to the dangers and risks presented by use of the drug. NPA also affirmatively avers that the FDA mandated a "black box" warning for lindane pesticidal treatments "to better inform both healthcare professionals and patients regarding the potential risks associated with the use and misuse of Lindane" because "[g]iven the possible risks associated with the use of Lindane, healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug events." NPA admits that in connection with the Public Health Advisory and the "black box" warning requirement adopted in 2003, the FDA mandated that lindane pesticidal treatments be distributed only in 1- or 2-ounce bottles. NPA further admits that there are dangers

associated with the misuse of lindane pesticidal treatments. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 9.

10. Lindane Lotion and Lindane Shampoo are named after their active ingredient, lindane. Historically, lindane was used primarily in an agricultural context—more than 99% of lindane was used agriculturally, while less than 1% was used pharmaceutically (e.g., 99.7% agricultural v. 0.3% pharmaceutical in 2006). The dangers associated with chronic occupational exposure to agricultural lindane have been widely and unfavorably reported. These dangers differ vastly from those associated with the short-term topical application of small amounts of Lindane medications to the hair and skin—just 4 minutes in the case of head lice.

ANSWER: NPA admits that Lindane Lotion and Lindane Shampoo are named for their active ingredient, the chemical lindane, but NPA denies that the word "lindane" necessarily means or refers to the products "Lindane Shampoo USP 1%" or "Lindane Lotion USP 1%." Further, NPA admits that lindane historically had been used agriculturally and that the dangers of occupational exposure to lindane have been unfavorably reported. NPA affirmatively avers that in 2006, the U.S. Environmental Protection Agency canceled all agricultural lindane product registrations, thereby phasing out all agricultural uses of lindane in the United States. NPA lacks sufficient information and knowledge to answer, and therefore denies, the allegations set forth in paragraph 10 regarding the percentage of lindane historically used agriculturally versus pharmaceutically. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 10.

11. Despite this well-documented scientific, medical, and regulatory history, the NPA has launched an attack campaign on Lindane medications. The NPA swaps agricultural and pharmaceutical research, selectively quoting and/or misstating findings from studies relating to the agricultural use of lindane, and widely disseminates false, misleading, and deceptive statements about the safety profile and effectiveness of Lindane medications. These statements have created confusion in the marketplace and affected purchasing and prescribing behavior, negatively impacting both the sale of Lindane medications and Morton Grove's business.

ANSWER: NPA denies all allegations set forth in paragraph 11.

Parties

12. Morton Grove, a Delaware corporation, is a pharmaceutical company with its principal place of business in Morton Grove, Illinois.

ANSWER: NPA admits the allegations set forth in paragraph 12.

13. Upon information and belief, the NPA, a Massachusetts corporation, is based in Needham, Massachusetts. The NPA widely distributes information and products nationally, including in Illinois, through its interactive websites www.headlice.org and www.lindane.org, which attract as many as 100,000 hits per day from thousands of unique visitors in the United States and around the world. The NPA sells its products nationally and has profited from the sales of the LiceMeister® comb in Illinois.

ANSWER: NPA admits that it is a Massachusetts corporation with its current principal place of business in Newton, Massachusetts, that it provides information on websites at www.headlice.org and www.lindane.org, that it has sold a medical device called the LiceMeister® Comb in Illinois and nationally, and that it offers the LiceMeister® Comb for sale on www.headlice.org. NPA further admits that www.headlice.org and www.lindane.org attract visitors located in the United States and around the world. NPA affirmatively avers that it is a non-profit corporation. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 13.

Jurisdiction & Venue

14. This Court has jurisdiction over the subject matter of this action based upon the federal question presented by the Lanham Act, 15 U.S.C. § 1125(a) et seq., pursuant to 28 U.S.C. § 1331, and supplemental jurisdiction of the state law claims pursuant to 28 U.S.C. § 1367.

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, NPA admits that the Court has subject-matter jurisdiction over this action.

15. The Court has jurisdiction over the NPA based on their substantial contacts with the State of Illinois, including their commission of tortious acts which caused injury in the State of Illinois.

ANSWER: Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, NPA admits that this Court has personal jurisdiction over NPA. NPA also admits that it has had substantial contact with the State of Illinois. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 15.

16. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

ANSWER: Paragraph 16 states a legal conclusion to which no response is required. To the extent a response is required, NPA admits that venue is proper in this Court.

Factual Allegations

I. Background on Lindane

17. Morton Grove is the sole United States distributor of Lindane Shampoo and Lindane Lotion.

ANSWER: NPA lacks sufficient information and knowledge to answer, and therefore denies, the allegations set forth in paragraph 17.

18. Lindane Lotion and Lindane Shampoo are prescription medications for the treatment of scabies, pubic lice, and head lice. These conditions are highly contagious public health conditions, some of which are sexually transmitted. These diseases affect adolescents, adults, and children, causing significant morbidity that impacts tens of millions of Americans.

ANSWER: NPA admits that Lindane Lotion is a second-line pesticidal scabies treatment available by prescription. NPA also admits that Lindane Shampoo is a second-line pesticidal treatment for pubic lice and head lice that is available by prescription. Further, NPA admits that scabies, pubic lice, or head lice may affect adolescents, adults, and children; that scabies and pubic lice can be sexually transmitted; and that scabies, pubic lice, and head lice are contagious. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 18.

19. Lindane medications have been used successfully in clinical practice for more than 50 years.

ANSWER: NPA admits that the chemical lindane has been used in pharmaceutical products in the United States for more than 50 years. Except as expressly admitted herein, NPA denies the allegations set forth in paragraph 19.

20. The FDA and the EPA, after numerous exhaustive reviews of the weight of evidence on Lindane medications, have concluded that currently approved medical uses of Lindane medications do not pose a significant risk to public health or safety. In fact, Lindane medications have been reviewed by the FDA more than a dozen times beginning in 1951, and with each review the "FDA has determined that lindane products have benefits that outweigh risks when used as directed." Woodcock, J. (Director, FDA Center for Drug Evaluation and Research), "Re: Docket No. 95P-0018/cP," Correspondence to Jill A. Cashen, Cancer Prevention Coalition, May 13, 1997; U.S. Food and Drug Administration, Lindane Assessment Memorandum (2003). In 2001, the EPA even downgraded the cancer classification of lindane to a level that is in fact lower than the most commonly used first-line, over-the-counter medication permethrin (active ingredient in Nix®), and concluded that no additional cancer risk assessments of lindane in humans were necessary.

ANSWER: NPA admits that the FDA has stated that the benefits of lindane pesticidal treatments outweigh their risks when they are used as directed and in accordance with the FDA's guidelines. NPA further admits that the FDA has reviewed lindane pesticidal treatments several times and that the result of each review has been to allow the treatments to remain available to treat lice or scabies, though with increasing restrictions on their use. NPA affirmatively avers that the FDA's increasing restrictions on the use of lindane pesticidal treatments include those set forth in the "black box" public health warning that the FDA mandated for lindane pesticidal treatments in 2003 to warn that these treatments "should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications," that "[s]eizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application according to directions,"

and that lindane pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity." NPA further affirmatively avers that a "black box" warning or "boxed warning" represents a stringent labeling requirement and reflects serious concerns on the part of the FDA as to the dangers and risks presented by use of the drug. NPA also affirmatively avers that the FDA mandated a "black box" warning for lindane pesticidal treatments "to better inform both healthcare professionals and patients regarding the potential risks associated with the use and misuse of Lindane" because "[g]iven the possible risks associated with the use of Lindane, healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug events." Finally, NPA affirmatively avers that the document cited in paragraph 20 as a 2003 "Lindane Assessment Memorandum" states in part that "lindane has a smaller safety margin than the other treatments available" and that "[t]he FDA has determined that there are other therapies for the treatment of head lice and scabies that may have less risk associated with them, and thus, the label states that 'lindane should be reserved for patients who have either failed to respond to adequate doses, or are intolerant of, other approved therapies.'" NPA admits that in 2001, the EPA's Cancer Assessment Review Committee "classified lindane into the category 'Suggestive evidence of carcinogenity'" and "recommended that quantification of human cancer risk is not required." NPA admits that as of December 2007, the EPA classified permethrin as "likely to be carcinogenic to humans by the oral route." Except as expressly admitted herein, NPA denies all allegations in paragraph 20.

21. The CDC and the American Academy of Pediatrics ("APA") both recommend pediculicidal treatments—which Lindane medications are considered—over wet combing for the management of head lice, as combing leads to dramatically lower rates of clinical cure compared with chemical treatments.

ANSWER: NPA admits that the CDC's current treatment guidelines for head lice state that a pediculicide should be used, in conjunction with a nit comb, to treat head lice. NPA admits that the American Academy of Pediatrics' current statement on the treatment of head lice states that a pediculicide should be used to treat head lice and that a nit comb can be used to remove nits. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 21.

II. The NPA Attempts to Increase Sales of the LiceMeister® by Distributing False, Misleading, and Deceptive Advertisements Regarding Lindane Medications

22. Blindly ignoring well-established science and the positions of the FDA, EPA, CDC, and APA on Lindane medications, the NPA has launched an attack campaign against Lindane medications in the hopes that it can increase sales of the LiceMeister® comb. This for-profit campaign blatantly ignores all standards for comparative marketing, including those promulgated by the FDA's Division of Drug Marketing and Advertising, which prohibit all such advertisements unless the representations made in those advertisements are supported by substantial evidence derived from adequate and well-controlled studies. *See* 21 U.S.C. § 355(d). Examples of the NPA's false advertising claims and other false statements referenced infra are attached as Exhibit A.

ANSWER: NPA denies all allegations set forth in paragraph 22.

23. In an effort to maximize profits, the NPA has falsely claimed that the "symptoms" from "exposure" to Lindane medications include:

> acute renal failure with azotemia, ADD/ADHD[,] anxiety, autism, atonia, agranulocytosis, aplastic anemia, anorexia, apprehensive mental state, behavior-mood disturbances, bullae, cancer, cardiac arrhythmias, clumsiness, coma, confusion, conjunctivitis, convulsions, cough, cyanosis, death, dermatitis, diaphoresis, diarrhea, disorientation, dizziness, dyspnea, emotional lability, excitement, excessive hair growth, fast heartbeat, fatigue, fever, giddiness, grinding teeth, headaches, heart palpitations, hematuria, hyperirritability, hypersensitivity, incoordination, kidney damage, liver damage, liver enlargement, loss of appetite, mania, mental

retardation, muscle cramps, muscle spasms, muscle tremors, nausea, nervousness, oliguria, pallor, paraesthesia, paresis, paresthesia, porphyria, proteinuria, pulmonary edema, restlessness, respiratory failure, seizures, shaking, sweating, tachycardia, tearing, thirst, trouble breathing, trouble swallowing, urticaria, vertigo, vomiting, weakness, wheezing, elevated LDH, GOT, GPT, alkaline phosphatase, ALT, AST enzymes.

ANSWER: NPA denies all allegations in paragraph 23.

24. In fact, the overwhelming majority of these so-called symptoms or side effects nowhere appear on the FDA-approved prescription label for Lindane Lotion or Lindane Shampoo and are not reflected in the events reported to the FDA through its Adverse Event Reporting System Database or to the manufacturer.

ANSWER: NPA admits that some of the side effects or medical conditions listed in paragraph 23 appear on the FDA-approved prescription labels for Lindane Lotion or Lindane Shampoo. NPA further admits that some of the side effects or medical conditions listed in paragraph 23 do not currently appear on the FDA-approved prescription labels for Lindane Lotion or Lindane Shampoo. NPA admits that some of the side effects or medical conditions listed in paragraph 23 are reflected in events reported to the FDA through its Adverse Event Reporting System Database. NPA lacks sufficient current and long-term information or knowledge to answer, and therefore denies, the allegations in paragraph 24 regarding whether each of the side effects or medical conditions listed in paragraph 23 is reflected in events reported to the FDA through its Adverse Event Reporting System Database or to the manufacturer. Except as expressly admitted herein, NPA denies all allegations in paragraph 24.

25. In addition to mischaracterizing the safety profile of Lindane medications, the NPA has also misclassified its regulatory status, claiming "Illinois Bans Lindane" and "Illinois Banned Lindane." The truth is that Illinois has not banned lindane. Following the filing of Morton Grove's complaint, the NPA removed these false statements from its website.

ANSWER: NPA admits that at one time, www.headlice.org contained a link titled "Illinois Bans Lindane" and contained the words "Illinois Banned Lindane," under which appeared an excerpt of the text of the Illinois bill to ban lindane and a link to information about its status and the Illinois House of Representatives' passage of the bill. NPA admits that after receiving a letter dated January 22, 2007 from Plaintiff's attorneys, it removed the link "Illinois Bans Lindane" and the words "Illinois Banned Lindane" from www.headlice.org, as well as the accompanying information about the Illinois bill. Further, NPA admits that Illinois has not currently banned lindane. NPA affirmatively avers that on April 8, 2005, the same date of the text posted on NPA's website, the Illinois House of Representatives passed a bill to ban lindane with 108 "aye" votes, zero "nay" votes, and one "present" vote. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 25.

26. The NPA's website also falsely claims that "one dose of a lindane treatment for head lice can pollute 6 million gallons of water to levels exceeding drinking water standards."

ANSWER: NPA denies all allegations set forth in paragraph 26.

27. Like many of the NPA's other statements, this statement is scientifically unsubstantiated and runs counter to the conclusions of subject matter experts working with the EPA. In fact, the EPA has determined in its most recent assessment of lindane that the amount of pharmaceutical lindane reaching drinking water supplies is insignificant and not of concern.

ANSWER: NPA denies all allegations set forth in paragraph 27.

28. Even unrealistic, worst-case estimates show that if Lindane medications were dumped directly into the drinking water supply (and not washed down the drain and out of the water supply and then diluted many thousand fold when reintroduced into large bodies of water as would normally occur), lindane levels would still be 67 to 333 times lower than the level considered safe by the EPA.

ANSWER: NPA denies all allegations set forth in paragraph 28.

29. These findings are further reinforced by real-world data from large-scale water contamination studies which show that lindane is not a water contaminant of concern, and that levels—when rarely detected—are well below standards established by the EPA for safe drinking. For example, a 2003 survey of water contamination, which involved the testing of 16,000 water systems serving 100 million people across US, conducted by the EPA found that 0% exceeded conservative levels considered safe. Federal Register 68(138) (July 18, 2003). Similar findings were noted by the United States Geological Survey in 1999 and 2000 where water samples near large cities and farms were tested across 30 states and all found to be well within established EPA standards. Kolpin DW, Furlong ET, Meyer MT, et al., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. streams, 1999-2000: A National Reconnaissance. *Environ Science Technology*, 2002; 36(6):1202-1211.

ANSWER: NPA admits that in 2003, the EPA published a survey of lindane concentrations in water in a 16-state region, derived from water samples collected between 1993 and 1997. NPA admits that a 2002 study by the United States Geological Survey of contaminants in U.S. streams in 1999 and 2000 included water samples in which amounts of lindane were detected. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 29.

30. In addition, an almost identical statement was retracted by the NPA's former co-defendant, the Ecology Center, Inc., who noted that the EPA "does not have risk concerns for concentrations of lindane in surface water used as a source of drinking water from consumer use [of lindane] for both lice and scabies." See http://www.ecocenter.org/safekids/clarifications.pdf.

ANSWER: NPA denies all allegations set forth in paragraph 30.

31. The NPA has received information from Morton Grove and others that its claim that "one dose of lindane" contaminates 6 million gallons of drinking water is false and misleading.

ANSWER: NPA denies all allegations set forth in paragraph 31.

32. Despite knowledge of this statement's falsity, it remains on the NPA's website today.

ANSWER: NPA denies all allegations set forth in paragraph 32.

33. The NPA does not stop there in its efforts to "scare" consumers into using its product, the LiceMeister® comb; it also attempts to convince consumers that using Lindane

medications cause cancer. For example, it argues that: "[T]he U.S. EPA classif[ies] lindane as a possible human carcinogen" and "Lindane should be handled as a **CARCINOGEN WITH EXTREME CAUTION**."

ANSWER: NPA admits that it reprinted on www.headlice.org a hazardous substances fact sheet published through the New Jersey Department of Health Right to Know Program that contained the statement "Lindane should be handled as a CARCINOGEN WITH EXTREME CAUTION," but NPA specifically denies that the words "CARCINOGEN WITH EXTREME CAUTION" appeared in bolded text. NPA admits that it reprinted on www.headlice.org a document titled "Statement in Support of the Elimination of Lindane Use in North America" and signed by 30 organizations, not including NPA, that contained the statement "The International Agency for Research in Cancer (IARC) and the U.S. EPA classify lindane as a possible human carcinogen." Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 33.

34. This statement is false and is not supported by the weight of scientific evidence or determinations published by the EPA, World Health Organization, and other subject matter experts.

ANSWER: NPA denies all allegations set forth in paragraph 34.

35. In fact, the NPA's former co-defendant, the Ecology Center, Inc. issued a retraction noting that current information on the EPA's website notes that the EPA updated the cancer classification of lindane in 2003 to "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans." See http://www.ecocenter.org/safekids/clarifications.pdf.

ANSWER: NPA denies all allegations set forth in paragraph 35.

36. Lindane's carcinogenic risk is now considered by the EPA to be on par with malathion (active ingredient in FDA-approved lice treatment Ovide) and even lower than the most commonly used first-line, over-the-counter treatment permethrin (active ingredient in Nix).

ANSWER: NPA admits that the EPA currently has "classified lindane into the category 'Suggestive evidence of carcinogenity, but not sufficient to assess human carcinogenic potential.'" NPA admits that as of 2006, the EPA classified malathion as having "suggestive evidence of carcinogenity." NPA admits that as of December 2007, the EPA classified permethrin as "likely to be carcinogenic to humans by the oral route." Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 36.

37. The NPA also has stated: "Case-controlled research shows a significant association between the incidences of brain tumors in children with the use of lindane-containing lice shampoos." There, however, have been no established links between the use of Lindane medications and the development of cancer, despite more than 50 years of clinical use on adults and children. The "case-controlled" research cited by the NPA prompted a special review by the FDA that subsequently concluded: "[I]t was unlikely that the data in the Davie et al. study established any link between the increased incidence of childhood brain cancer and the use of Lindane 1%...shampoo, and that there was no need to make any changes in the current labeling for [Lindane medications]."

ANSWER: NPA admits that it reprinted on www.headlice.org a document titled "Statement in Support of the Elimination of Lindane Use in North America" and signed by 30 organizations, not including NPA, that contained the statement "Case-controlled research shows a significant association between the incidences of brain tumors in children with the use of lindane-containing lice shampoos." NPA admits that in 1993, the FDA evaluated the discussion of lindane pesticidal treatments in the following study, Davis, James R., *et al.*, "Family Pesticide Use and Childhood Brain Cancer," *Archives of Environmental Contamination & Toxicology*, 24:87-92 (1993), and that the overall result of the FDA's evaluation was to allow lindane pesticidal treatments to remain on the market. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 37.

38. The NPA has also claimed that: "Lindane, first used as a smoke bomb during WWI, is an endocrine disrupting, bio-accumulative and toxic chemical. It is a known health risk to humans, especially children, with potential adverse effects ranging from learning disabilities, to birth defects, to breast cancer, to leukemia, to seizures, to death."

ANSWER: NPA admits that the statement "Lindane, first used as a smoke bomb during WWI, is an endocrine disrupting, bio-accumulative and toxic chemical. It is a known health risk to humans, especially children, with potential adverse effects ranging from learning disabilities, to birth defects, to breast cancer, to leukemia, to seizures, to death." was posted on www.headlice.org. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 38.

39. With respect to the NPA's allegation that the use of lindane medications is associated with leukemia, the NPA's former co-defendant, the Ecology Center, retracted a similar statement, which notes that in this particular study, only "[s]ix of the 568 children participating in this study were treated with lindane shampoo." As the Ecology Center conceded, the study's only conclusion with respect to lindane medications was that the issue "requires further study" in light of the "reported 95% confidence interval for lindane was CI 0.5 to 8.7," which is not statistically significant. See http://www.ecocenter.org/safekids/clarifications.pdf.

ANSWER: NPA denies all allegations set forth in paragraph 39.

40. In a further effort to divert customers from Lindane medications to the LiceMeister® comb, the NPA's website also contains the following false and deceptive statements and misleading "warnings":

- "Be Sure You Provide a Non-Chemical Choice For Your Children .... Because it's not worth taking unnecessary risks when the bottom line will always be the manual removal of lice and nits."
- "Never resort to **dangerous remedies** such as lindane, kerosene, or pet shampoos." (emphasis supplied).
- "When used for early detection and manual removal, the LiceMeister comb is the realistic and practical alternative to unnecessary and potentially harmful pesticides. The LiceMeister is the safe and cost effective way to win the war against head lice and keep the kids in school safe, lice and nit free."

- "Do not recommend products containing lindane. The Food and Drug Administration (FDA) regards it as potentially more toxic than all other pediculicidal choices and no more effective."

ANSWER: NPA denies all allegations set forth in paragraph 40.

41. Finally, in an effort to sell additional LiceMeister® combs, the NPA has attempted to scare potential and actual consumers of Lindane medications with a "parade of horribles" regarding the effects of occupational exposure to agricultural lindane. These statements include:

- "Lindane is quite toxic to humans. The acute (short-term) effects of lindane through inhalation exposure in humans consist of irritation of the nose and throat and effects on the blood and skin. Chronic (long-term) exposure to lindane by inhalation in humans has been associated with effects on the liver, blood, and nervous, cardiovascular, and immune systems."

- "Chronic effects include damage to the nervous system and liver disease. Worker exposures have resulted in blood disorders, headaches, convulsions, and disruption of the reproductive hormones of the endocrine system."

ANSWER: NPA denies all allegations set forth in paragraph 41.

42. These statements are wildly misleading in context, as the FDA has concluded that the "risk of occupational/environmental exposure should be assessed separately and independently of the risk related to the therapeutic use of a medication to treat a medical condition where there is a direct benefit to the patient." The EPA shares this position.

ANSWER: NPA admits that an FDA memorandum from 2003 regarding lindane contains the following paragraph: "Work related and environmental exposures to high and persistent concentrations of lindane initially led to concerns regarding the safety of this pesticide. In contrast to therapeutic use, exposures secondary to environmental use result in no direct benefit for the exposed persons. This risk of occupational/environmental exposures should be assessed separately and independent of the risk related to the therapeutic use of a medication to treat a medical condition where there is a direct benefit to the patient." Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 42.

43. Indeed, the NPA's former co-defendant, the Ecology Center, Inc. published a retraction that clarifies this, noting that "the majority of such [adverse reactions] have resulted from oral ingestion (which is not how lindane medications are directed to be applied.)" See http://www.ecocenter.org/safekids/clarifications.pdf.

ANSWER: NPA denies all allegations set forth in paragraph 43.

44. Upon information and belief, the NPA has never performed, prior to publication of the aforementioned statements, any tests comparing the qualities and characteristics of the LiceMeister® comb and Lindane medications, or evaluating the qualities and characteristics of Lindane medications.

ANSWER: NPA admits that it has not conducted studies that directly compare the qualities and characteristics of the medical device the LiceMeister® Comb to the qualities and characteristics of lindane pesticidal treatments used to treat lice. NPA admits that it has not conducted tests as to the physical or chemical properties of lindane pesticidal treatments. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 44.

III. As a Result of the NPA's Actions, Morton Grove Has Been Harmed

45. As a result of the NPA's foregoing statements, Morton Grove has suffered incalculable financial and reputational injury to its business, including lost sales of Lindane medications and diminished goodwill.

ANSWER: NPA denies all allegations set forth in paragraph 45.

46. The NPA's statements, for example, contributed to a decrease in Morton Grove's sales of 23%, or $9.3 million, from January 2006 to November 2006.

ANSWER: NPA denies all allegations set forth in paragraph 46.

47. The NPA's statements are viewed up to 100,000 times per day on the NPA's website, and they have deceived consumers and physicians into falsely questioning the safety and effectiveness of Lindane medications, thereby materially affecting purchasing and prescribing behavior for Lindane medications.

ANSWER: Paragraph 47 contains legal conclusions to which no response is required. To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 47.

48. Moreover, the NPA has crafted its website in a manner to most effectively disseminate the aforementioned false and misleading statements, directing users to "see what we want them to see and avoid what we don't."

ANSWER: NPA denies all allegations set forth in paragraph 48.

49. The NPA itself has acknowledged that its statements have affected Morton Grove's sales, noting that "sales figures for lindane products (Kwell, etc.) have fallen dramatically …By targeting parents for re-education along with health professionals, we have ensured that the message travels up as well as down, and takes root in the process."

ANSWER: NPA denies all allegations set forth in paragraph 49.

IV. The NPA's Statements Were Made Intentionally & Maliciously

50. In light of the statements' significant impact on Morton Grove's business, Morton Grove sent the NPA a letter (attached as Exhibit B) indicating that the NPA was publishing false, misleading, and deceptive statements about Lindane medications which were harming Morton Grove. This letters detailed each such false statement (either identical or similar to those included in this complaint), provided factual support for why each statement was false, and gave the NPA time to retract such statements. In addition, Morton Grove previously filed suit against the NPA on February 6, 2007 in the Northern District of Illinois (No. 06-CV-3815), from which this action was severed.

ANSWER: NPA admits that it received a letter dated January 22, 2007 from Morton Grove's attorneys, Winston & Strawn, that Morton Grove previously filed suit against NPA on February 6, 2007, in the U.S. District Court for the Northern District of Illinois (Case No. 06-CV-3815), and that Morton Grove's claims against NPA were severed from that prior action on November 30, 2007. NPA affirmatively avers that upon receiving the January 22, 2007 letter from Morton Grove's attorneys, it requested time to evaluate the

allegations, but Morton Grove chose instead to file suit. Except as expressly admitted herein, NPA denies all allegations set forth in paragraph 50.

51. Despite this opportunity, the NPA failed to retract its false, misleading, and deceptive statements and continues to allow the publication and dissemination of these statements, even after receiving information that certain of these statements were false.

ANSWER: NPA otherwise denies all allegations set forth in paragraph 51.

52. The NPA's continued publication of these statements, despite knowing their falsity, demonstrates the NPA's malicious intent to inflict harm on Morton Grove.

ANSWER: NPA denies all allegations set forth in paragraph 52.

COUNT I
LANHAM ACT (15 U.S.C. § 1125(a))

53. Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through 52 of this Complaint.

ANSWER: NPA incorporates by reference and realleges as if fully set forth herein its answers to the allegations contained in paragraphs 1-52.

54. The NPA sells a lice treatment product called the LiceMeister®, which it promotes as an alternative to Lindane medications.

ANSWER: NPA admits that it sells a medical device called the LiceMeister® Comb. Except as expressly admitted herein, NPA denies the allegations set forth in paragraph 54.

55. The NPA's statements, through its website and sales of its product, have been made in interstate commerce and were, are, and continue to be made intentionally and willfully.

ANSWER: NPA admits that the statements attributed to NPA and identified in paragraphs 23, 25, 26, 33, 37, 38, 40, and 41 were made in interstate commerce. Paragraph 55 contains legal conclusions to which no response is required. To the extent

these legal conclusions can be construed as allegations of fact, NPA denies them. Except as expressly admitted, NPA denies all allegations set forth in paragraph 55.

56. The NPA's advertising claims set forth above are false and misleading descriptions and representations of fact about Lindane medications. In addition, these statements are misleading in context and violate Section 43(a) of the Lanham Act, 15 U.S.C.§ 1125(a).

ANSWER: Paragraph 56 contains legal conclusions to which no response is required. To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 56.

57. The NPA's false and misleading advertising claims have deceived and have the tendency to deceive a substantial portion of the target audience for lice and scabies treatments.

ANSWER: Paragraph 57 contains legal conclusions to which no response is required. To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 57.

58. The NPA's false and misleading advertising claims are material to consumers' purchasing decisions.

ANSWER: Paragraph 58 contains legal conclusions to which no response is required. To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 58.

59. The NPA has caused its false and misleading advertising claims to enter into interstate commerce.

ANSWER: Paragraph 59 contains legal conclusions to which no response is required. To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 59.

60. The NPA's false and misleading advertising claims have caused certain consumers to not purchase Lindane medications. These claims have caused and are continuing to cause

damage to Morton Grove's sales and market share and injury to Morton Grove's goodwill and business reputation, warranting injunctive relief.

ANSWER: Paragraph 60 contains legal conclusions to which no response is required. To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 60.

61. The NPA's false and misleading claims were made deliberately and willfully, and the NPA knew or should have known that these statements were false and that the impact of its statements would be to reduce sales of Lindane medications. Therefore, Morton Grove seeks a finding that this is an exceptional case, requiring an award of attorney fees to Morton Grove.

ANSWER: NPA denies all allegations set forth in paragraph 61.

62. The NPA's continued use of false or misleading advertising claims is causing great, irreparable injury to Morton Grove, thereby warranting an order granting permanent injunctive relief.

ANSWER: NPA denies all allegations set forth in paragraph 62.

COUNT II
TRADE DISPARAGEMENT

63. Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through 62 of this Complaint.

ANSWER: NPA incorporates by reference and realleges as if fully set forth herein its answers to the allegations contained in paragraphs 1-62.

64. The NPA published and communicated to third persons the statements regarding Lindane medications set forth in Paragraphs 23 through 42.

ANSWER: NPA denies all allegations set forth in paragraph 64.

65. The statements regarding Lindane medications set forth in Paragraphs 23 through 42 are false and misleading.

ANSWER: Paragraph 65 contains legal conclusions to which no response is required. To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 65.

66. The NPA published and communicated these statements through its website and other means.

ANSWER: NPA denies all allegations set forth in paragraph 66.

67. When the NPA published and communicated these statements and refused to retract them, it did so with knowledge of their falsity or reckless disregard for their truth, and with the intent to inflict economic harm upon Morton Grove.

ANSWER: Paragraph 67 contains legal conclusions to which no response is required. To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 67.

68. As a result of the NPA's statements, Morton Grove suffered specific harm as detailed in Paragraphs 45 through 49.

ANSWER: NPA incorporates by reference and realleges as if fully set forth herein the answers to the allegations contained in paragraphs 45-49. NPA otherwise denies all allegations set forth in paragraph 68.

COUNT III
ILLINOIS DECEPTIVE TRADE PRACTICES ACT (815 ILCS 510/2)

69. Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through 68 of this Complaint.

ANSWER: NPA incorporates by reference and realleges as if fully set forth herein its answers to the allegations contained in paragraphs 1-68.

70. The NPA published and communicated to third persons the statements regarding Lindane medications set forth in Paragraphs 23 through 42.

ANSWER: NPA denies all allegations set forth in paragraph 70.

71. The statements regarding Lindane medications set forth in Paragraphs 23 through 42 are false and misleading.

ANSWER: NPA denies all allegations set forth in paragraph 71.

72. When the NPA published and communicated these statements and refused to retract them, it did so with knowledge of their falsity or reckless disregard for their truth, and with the intent to inflict economic harm upon Morton Grove. Specifically, prior to filing its Complaint, Morton Grove provided the NPA with specific scientific proof that certain of its statements were false and misleading. The NPA did not substantively respond to Morton Grove's letter.

ANSWER: Paragraph 72 contains legal conclusions to which no response is required.

To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 72.

73. These statements violated multiple sections of 815 ILCS 510/2, including subsections (2), (7), (8), and (12).

ANSWER: Paragraph 73 contains legal conclusions to which no response is required.

To the extent these legal conclusions can be construed as allegations of fact, NPA denies them. NPA otherwise denies all allegations set forth in paragraph 73.

74. As a result of the NPA's statements, Morton Grove suffered specific harm as detailed in Paragraphs 45 through 49.

ANSWER: NPA denies the allegations set forth in paragraph 74.

AFFIRMATIVE AND OTHER DEFENSES

1. Plaintiff cannot state any claim upon which relief can be granted.

2. Plaintiff cannot state any claim upon which relief can be granted based on NPA's statements that constitute opinion or puffery.

3. Plaintiff cannot state any claim upon which relief can be granted because NPA's statements are not "of and concerning" Plaintiff or its products.

4. Plaintiff lacks standing to bring a false advertising claim under the Lanham Act because it is not NPA's competitor.

5. Plaintiff lacks standing to bring a false advertising claim under the Lanham Act because it has not suffered the requisite competitive injury.

6. Plaintiff cannot state a claim for trade disparagement, violation of the Lanham Act, or violation of the Illinois Deceptive Trade Practices Act because Plaintiff cannot show that NPA made false or misleading assertions of fact about Plaintiff's products.

7. Plaintiff cannot state a claim under the Lanham Act or the Illinois Deceptive Trade Practices Act because the alleged NPA statements at issue were not made in commercial advertising or promotion.

8. Plaintiff cannot state a claim under the Lanham Act or the Illinois Deceptive Trade Practices Act because the alleged NPA statements at issue did not actually deceive and have no tendency to deceive a substantial segment of their audience.

9. Plaintiff cannot state a claim under the Lanham Act or the Illinois Deceptive Trade Practices Act because the alleged NPA statements at issue were not material or otherwise likely to influence the purchasing decision.

10. Plaintiff cannot state a claim under the Lanham Act or the Illinois Deceptive Trade Practices Act because Plaintiff cannot show the alleged NPA statements at issue caused a direct diversion of sales from Plaintiff to NPA or a loss of goodwill associated with Plaintiff's products.

11. Plaintiff cannot state a claim for trade disparagement because Illinois no longer recognizes a common law cause of action for trade disparagement.

12. All of Plaintiff's claims are barred by the First and Fourteenth Amendments to the United States Constitution.

13. All of Plaintiff's claims are barred by Article One, Section Four of the Illinois Constitution.

14. All of Plaintiff's claims are barred because NPA's statements are protected by qualified and other privileges.

15. Plaintiff cannot prevail on any of its claims because Plaintiff cannot provide clear and convincing evidence that NPA published the statements at issue with actual malice.

16. Plaintiff is not entitled to injunctive relief because it has not suffered an irreparable injury.

17. Plaintiff's claims for injunctive or other equitable relief are precluded by the First Amendment.

18. Plaintiff's claims are barred by the applicable statute of limitations.

19. Plaintiff's claims are barred by the doctrine of laches.

20. The doctrine of laches precludes Plaintiff from obtaining injunctive or other equitable relief.

21. The doctrine of unclean hands precludes Plaintiff from obtaining injunctive or other equitable relief.

22. Plaintiff cannot recover attorneys' fees because NPA did not act intentionally, willfully, or maliciously.

WHEREFORE, NPA respectfully requests that this Court enter judgment for NPA and against Plaintiff and grant NPA such other relief as this Court deems appropriate.

COUNTERCLAIM

Counterclaim Plaintiff The National Pediculosis Association, Inc. ("NPA"), by and through its attorneys, Jenner & Block LLP, for its Counterclaim against Morton Grove Pharmaceuticals, Inc. ("Morton Grove"), states as follows:

Nature of Action

1. Morton Grove manufactures and sells two prescription pesticidal treatments containing the chemical lindane: Lindane Lotion USP 1% ("Lindane Lotion"), which is used as a second-line treatment for scabies, and Lindane Shampoo USP 1% ("Lindane Shampoo"), which is used as a second-line treatment for head lice. Over the last fifteen years, in light of the toxicity and dangers of pharmaceutical lindane, the U.S. Food and Drug Administration ("FDA") and other government entities have imposed increasingly stringent restrictions on the packaging, labeling, and approved uses of pharmaceutical lindane products, including Lindane Lotion and Lindane Shampoo. Today these products are banned in California and may be sold elsewhere in the United States only in single-use packages containing a "black box" warning that details some of the reported risks of their use, which include "[s]eizures and deaths."

2. In response to these events, Morton Grove has actively engaged in an aggressive and targeted promotional campaign designed to mislead both consumers and health professionals about the dangers of Lindane Shampoo and Lindane Lotion.

3. As part of this campaign, Morton Grove has advertised and promoted its lindane pesticidal treatments in a manner that disregards, downplays, and discounts their serious risks and use restrictions, including those contained in the FDA's mandated "black box" public health warning for Lindane Shampoo and Lindane Lotion.

4. Also as part of this campaign, Morton Grove has sought to discredit NPA and other organizations that warn about the dangers of the chemical lindane and its use in lice and scabies treatments.

5. NPA brings this counterclaim to redress the false and misleading statements made by Morton Grove regarding NPA and Morton Grove's lindane products.

6. NPA asserts a claim against Morton Grove for violation of the Illinois Deceptive Trade Practices Act.

7. In its Complaint, Morton Grove has alleged that NPA's LiceMeister® Comb competes with Morton Grove's products, Lindane Lotion and Lindane Shampoo. As set forth in its Answer and Affirmative Defenses above, NPA denies that its product, the LiceMeister® Comb, competes with Lindane Lotion and/or Lindane Shampoo. Thus, NPA's primary position is that it is not a competitor of Morton Grove, and that Morton Grove does not have standing to maintain its Lanham Act claim against NPA. Nevertheless, should the Court determine that NPA and Morton Grove are competitors, NPA would also have standing to assert a claim against Morton Grove under the Lanham Act based on Morton Grove's misleading advertising and promotion of its products. Accordingly, as an alternative position, and without waiving its primary position that Morton Grove and NPA are not competitors, NPA also asserts against Morton Grove a Lanham Act claim arising out of the same underlying conduct as NPA's claim for violation of the Illinois Deceptive Trade Practices Act.

Parties

8. NPA is a Massachusetts non-profit organization dedicated to protecting children from the misuse and abuse of potentially harmful lice and scabies pesticidal treatments. Its principal place of business is in Newton, Massachusetts.

9. Morton Grove is a pharmaceutical company that manufactures and distributes Lindane Shampoo and Lindane Lotion. Morton Grove's principal place of business is in Morton Grove, Illinois.

Jurisdiction and Venue

10. Pursuant to 28 U.S.C. § 1391, this Court has jurisdiction over the subject matter of this action based upon the federal question presented by the Lanham Act, 15 U.S.C. § 1125(a) *et. seq*. This Court has supplemental jurisdiction of NPA's claims against Morton Grove pursuant to 28 U.S.C. § 1367.

11. The Court has jurisdiction over Morton Grove because it is an Illinois resident and otherwise has substantial contacts with the State of Illinois.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(1) and/or § 1391(b)(2).

Factual Allegations

13. The chemical lindane is an organochlorine pesticide and a neurotoxicant. It has been used both as an agricultural pesticide and as the active ingredient in pesticidal treatments used to treat head lice and scabies, including Morton Grove's products, Lindane Shampoo and Lindane Lotion.

Increasing State and Federal Regulation of Pharmaceutical Use of Lindane

14. The dangers and risks associated with the chemical lindane, including its use in lice and scabies pesticidal treatments, have attracted increasing attention in recent years from regulatory agencies and international and domestic governmental bodies.

15. In 1995, the FDA determined that lindane pesticidal treatments were not as safe as other lice and scabies treatment options and mandated that lindane pesticidal treatments be

available only as second-line therapies "because there are safer alternatives that should be used first," meaning they are to be prescribed only for "patients who have either failed to respond to adequate doses, or are intolerant of, other approved therapies."

16. In 2000, the State of California banned the use or sale in the state of "any product used for the treatment of lice or scabies in human beings that contains the pesticide Lindane" in part because it concluded that "[l]indane is less effective and has more potential toxicity than the easily available alternatives." This legislation took effect on January 1, 2002.

17. Since 2002, bills to ban pharmaceutical uses of the chemical lindane have been introduced in several states, including at least New York, Michigan, and Illinois.

18. In 2003, the FDA issued a Public Health Advisory warning of the serious risks in using Lindane Lotion and Lindane Shampoo for the treatment of scabies and lice. The Advisory cited a variety of concerns about lindane pesticidal treatments, including the risk of neurologic side effects ranging from dizziness to seizures. The Advisory also warned that Lindane Lotion and Lindane Shampoo "is contraindicated for use in neonates and should be used with extreme caution in children and individuals weighing less than 50 kg (110 lbs)."

19. In its Public Health Advisory, the FDA explained that serious side effects can arise from misuse of lindane pesticidal treatments, as well as from use according to labeled instructions. For example, the FDA warned that "[i]n post-marketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia."

20. In conjunction with this Public Health Advisory, the FDA mandated new labeling and packaging requirements for Lindane Lotion and Lindane Shampoo, including the addition of a "black box" public health warning.

21. A "black box" warning or "boxed warning," such as that required for Lindane Shampoo and Lindane Lotion, represents a stringent labeling requirement and reflects serious concerns on the part of the FDA as to the dangers and risks presented by use of the drug.

22. According to the black box, Lindane Lotion or Lindane Shampoo "should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications."

23. The black box emphasizes that the adverse effects associated with lindane pesticidal treatments have occurred even when they are used as directed: "Seizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application according to directions."

24. The black box also explains that lindane pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity."

25. In 2006, the U.S. Environmental Protection Agency banned the chemical lindane from use in the United States as an agricultural pesticide. According to Pesticide Action Network North America, the chemical lindane is banned in at least 52 countries, and its use is severely restricted in at least 33 others. International efforts to ban the chemical lindane continue.

Morton Grove's Marketing And Promotion Of Its Lindane-Containing Products

26. In response to the increasing scrutiny of the chemical lindane and its pharmaceutical uses, Morton Grove launched an aggressive advertising and promotional

campaign designed to minimize the dangers and risks of using Lindane Shampoo and Lindane Lotion, including those identified in the FDA's "black box" warning.

27. Morton Grove's advertising campaign has included direct mailing campaigns; traditional print advertising; targeted mailing campaigns, including newsletters mailed to school nurses; personal promotion to physicians, pharmacists, and others through use of a sales force; distribution of "patient education" materials; sales force attendance at conventions and association meetings; creation and maintenance of two websites, www.lindane.com and www.lindanetruth.com; and intensive letter-writing initiatives, particularly directed toward health professionals located in states where pharmaceutical lindane has received legislative attention.

28. In particular, as part of its strategy to ensure continued use of Lindane Shampoo and Lindane Lotion, Morton Grove has targeted pediatricians and other health care professionals. Morton Grove seeks to convince them to write prescriptions for, or recommend use of, these products despite the increasing regulatory scrutiny of pharmaceutical lindane, and despite the risks described in the FDA's black box warning and elsewhere.

The FDA Warning Letter

29. Morton Grove's aggressive promotional campaign recently prompted action by the FDA.

30. On December 13, 2007, the FDA sent Morton Grove a Warning Letter ("the Warning Letter," attached hereto as Exhibit A) informing Morton Grove that some of its advertising and promotional material contained false or misleading statements about Lindane Shampoo.

31. In the Warning Letter, the FDA described portions of previous promotional websites for Lindane Shampoo and Morton Grove's promotional newsletters as "misleading in that they omit and/or minimize the most serious and important risk information associated with the use of Lindane Shampoo, particularly in pediatric patients; include a misleading dosing claim; and overstate the efficacy of Lindane Shampoo." Further, the FDA chastised Morton Grove because the identified advertising "materials convey[ed] little sense of [the] limitation [of lindane pesticidal treatments as second-line options] and little about the magnitude and nature of the risks associated with the drug."

32. The FDA concluded in the Warning Letter that Morton Grove's advertising materials "appear[ed] to represent an attempt to downplay the significant risks associated with Lindane Shampoo use and encourage wider use, with less care, than is appropriate under approved labeling."

33. Accordingly, the FDA told Morton Grove:

> We are very concerned about the potential for significant negative health consequences in children who use Lindane Shampoo because you are promoting Lindane Shampoo as being safer and more effective for pediatric patients than has been demonstrated by substantial evidence or substantial clinical experience . . . .

34. In addition to the print marketing materials described in the FDA Warning Letter, Morton Grove has made other misleading claims while advertising Lindane Lotion and Lindane Shampoo. Not only did Morton Grove disseminate additional misleading materials prior to receiving the FDA Warning Letter, but it also continued to do so after receiving that letter, which pointed out the misleading nature of its promotional claims.

Morton Grove's Misleading Letters to Pediatricians and Other Health Care Professionals

35. In or around May 2006, Morton Grove launched an aggressive letter-writing campaign in the state of Michigan, seeking to promote its lindane products and downplay their dangers.

36. In May 2006, Morton Grove sent at least five letters (the "Letters") to pediatricians and other health care professionals located in Michigan. Copies of the Letters are attached hereto as Exhibits B-F.

37. The Letters tout the benefits of Morton Grove's lindane products and contain misleading information about the safety and efficacy of those products.

38. Moreover, by directing the Letters to pediatricians and other health care professionals who treat or work with children, Morton Grove falsely and misleadingly implied that its lindane-containing products are generally appropriate for use on children.

39. On information and belief, the health care professionals receiving the Letters have influence and standing in their profession and community.

40. On information and belief, Morton Grove has also sent letters touting the benefits of its lindane products to other health care professionals in Michigan.

41. On information and belief, these letters contained statements similar to those contained in Exhibits B-F.

42. On information and belief, Morton Grove has also sent letters touting the benefits of its lindane products to health care professionals outside Michigan.

43. On information and belief, these letters contained statements similar to those contained in Exhibits B-F.

44. Morton Grove intended that the Letters would influence the recipients' positions on and decisions to use, prescribe, or recommend Morton Grove's lindane products.

45. On information and belief, Morton Grove did not take steps to correct the misleading impressions created by these letters, even after it received the FDA Warning Letter emphasizing the misleading nature of its other materials promoting its lindane products.

Morton Grove's Letter to the Executive Director of the Wayne County Medical Society of Southeast Michigan

46. Morton Grove sent a letter dated May 5, 2006, and signed by Dr. Chang Lee (identified as Morton Grove's vice president of regulatory affairs and clinical research), to Adam Jablonowski, listed as the Executive Director of the Wayne County Medical Society of Southeast Michigan. (Ex. B at MGP001036-40.)

47. Morton Grove's letter to Dr. Jablonowski contains statements that downplay the risks of lindane pesticidal treatments.

48. Specifically, the letter identified in paragraph 46 includes the following statement: "The fact is that tens of millions of prescriptions for lindane medications have been written in the 50+ years they have been on the U.S. market, yet relatively few adverse events have been reported."

49. That letter also includes the following statement: "The great majority of these events, 85% were non-serious, and serious events most often resulted from product misuse—80% of cases (note that in 2003, lindane medications were limited to small, single-use 2 oz. bottle to minimize this risk)."

50. The statements set forth in paragraphs 48 and 49 were repeated in an enclosure that, on information and belief, was included with the letter identified in paragraph 46. (Ex. B at MGP001060-68.)

51. The enclosure identified in paragraph 50 also contains the following statement: "From 1951 through 2002, only 3 deaths confirmed to be related to lindane medications were reported through the FDA AERS [Adverse Event Reporting System] database. In each instance, these medications were misused (see claims #1 and #3)."

Morton Grove's Letter to the Chief of Staff of the Children's Hospital of Michigan

52. Morton Grove sent a letter dated May 5, 2006 and signed by Dr. Lee to Dr. Mary Lu Angelilli, identified in the letter as the Chief of Staff of the Children's Hospital of Michigan, located in Detroit. (Ex. C at MGP001041-44.)

53. The letter identified in paragraph 52 included the statements set forth in paragraphs 48 and 49, and the enclosure identified in paragraphs 50 and 51.

Morton Grove's Letter to the President of the Michigan Chapter of the American Academy of Pediatrics

54. Morton Grove sent a letter dated May 5, 2006 and signed by Dr. Lee to Dr. Sheila Gahagan, identified in the letter as the President of the Michigan Chapter of the American Academy of Pediatrics. (Ex. D at MGP001045-49.)

55. The letter identified in paragraph 54 included the statements set forth in paragraphs 48 and 49, and the enclosure identified in paragraphs 50 and 51.

Morton Grove's Letter to the Executive Director of the Michigan Nurses' Association

56. Morton Grove sent a letter dated May 5, 2006 and signed by Dr. Lee to Tom Bissonnette, identified in the letter as the Executive Director of the Michigan Nurses Association. (Ex. E at MGP001050-53.)

57. The letter identified in paragraph 56 included the statements set forth in paragraphs 48 and 49, and the enclosure identified in paragraphs 50 and 51.

Morton Grove's Letter to the President of the Michigan Council for Maternal and Child Health

58. Morton Grove sent a letter dated May 5, 2006 and signed by Dr. Lee to Paul N. Shaheen, identified in the letter as the President of the Michigan Council for Maternal and Child Health. (Ex. F at MGP001054-58.)

59. The letter identified in paragraph 58 included the statements set forth in paragraphs 48 and 49, and the enclosure identified in paragraphs 50 and 51.

Morton Grove's Use of Misleading Websites to Promote its Lindane Products

60. Even after receiving the FDA Warning Letter, Morton Grove has continued to promote its lindane products by using misleading statements about their safety and efficacy.

61. On information and belief, Morton Grove owns and operates the following websites: www.lindane.com and www.lindanetruth.com.

62. These two websites are one component of Morton Grove's overall marketing and advertising strategy regarding its products, Lindane Shampoo and Lindane Lotion. These websites function as an important portal for non-personal selling of Morton Grove's lindane products.

63. The websites www.lindane.com and www.lindanetruth.com contain the following statements:

> The FDA has quantified serious adverse events (AEs) as rare when lindane pediculicides are used properly—an assessment that is based on more than 50 years of prescription use in tens of millions of patients. The fact is that lindane pediculicides are generally safe and well tolerated. The most common side effects are nonserious reactions of the skin, such as itching and dryness.

The portions of these websites containing these statements are attached hereto as Exhibit G.

64. The portions of these websites containing the statements set forth in paragraph 63 do not mention that the adverse events reported after the use of lindane pesticidal treatments have included serious events such as seizures and death.

65. To further mislead the public and health professionals about the safety of lindane pesticidal treatments, Morton Grove also has sought the assistance of purported "experts" and posted on its websites testimonial letters touting the supposed safety of lindane pesticidal treatments.

66. Morton Grove posted these letters on www.lindane.com and www.lindanetruth.com on web pages titled, "Medical & Scientific Opinions." The individual letters appear on a list of links that also includes documents created by governmental and other agencies, including the FDA and EPA, implying that these letters are credible sources of information about Morton Grove's lindane products.

Misleading Statements in Testimonial Letter from Dr. Tor Shwayder

67. A letter dated June 12, 2007, from Tor Shwayder, identified as a Fellow in the American Academies of Pediatrics, a Fellow in the American Academies of Dermatology and in the American Academies of Pediatrics, a boarded pediatric dermatology physician, and Director of both Pediatric Dermatology and the Dermatology Residency Program at the Henry Ford Medical Center, is posted on Morton Grove's websites at www.lindane.com/pov/mso/ and www.lindanetruth.com/pov/mso/. Copies of this letter, as it appears on both websites, are attached hereto as Exhibit H.

68. In his letter, Dr. Shwayder states: "Lindane is safe, effective, it is not toxic if used as directed" and "[m]y training in both pediatrics and dermatology allows me to judge this issue."

69. The letter further states: "The University of Michigan Medical School taught the use of Lindane for scabies and lice during my training there. The same was true of my pediatric residency at U of M."

70. The letter further states regarding lindane pesticidal treatments: "I have even used it on myself, my children and my pregnant wife." Later on in the letter, he adds: "[T]hat fetus exposed to Lindane when my wife used it, what happened to her? She just finished her freshman year at Harvard with stellar grades in high-level courses. Don't let these alarmist anti-Lindane advocates scare you into thinking Lindane is a dreadful neurotoxin. It just isn't so."

71. Nowhere in the letter identified in paragraph 67 does Dr. Shwayder mention that the FDA's labeling guidelines on lindane pesticidal treatments explicitly warn that "Lindane Shampoo [or Lindane Lotion] should be given to pregnant women only if clearly needed. There are no adequate and well-controlled studies of Lindane Shampoo [or Lindane Lotion] in pregnant women."

Misleading Statements in Testimonial Letter from Dr. Adelaide A. Hebert

72. A letter dated May 25, 2007 from Dr. Adelaide A. Hebert, identified as a professor of dermatology at the University of Texas Medical School and the president of the Society for Pediatric Dermatology, is posted on Morton Grove's websites at www.lindane.com/pov/mso/ and www.lindanetruth.com/pov/mso/. Copies of this letter, as it appears on both websites, are attached hereto as Exhibit I.

73. In her letter, Dr. Hebert states: "I have enclosed some photographs of a two-year-old girl who was previously treated for scabies with oral Ivermectin, one of the most potent medications on the market. The patient failed Ivermectin therapy and was subsequently treated successfully with Lindane."

74. The letter further states: "As the current President of the Society for Pediatric Dermatology, I can strongly attest to the value of Lindane for pediatric patients who suffer from scabies and lice. I have personally used this medication many times during my 21-year career in pediatric dermatology, and believe that it is both safe and effective when used according to the package insert."

75. Nowhere in the letters identified in paragraphs 67 and 72 do Dr. Shwayder or Dr. Hebert mention that the FDA's "black box" warning requires lindane pesticidal treatments to be used "with caution" in anyone weighing less 110 pounds – in other words, most children.

Morton Grove's Misleading Suggestions That Lindane Pesticidal Treatments Are Safe If Used Properly

76. The statements set forth in paragraphs 48-49, 51, and 63 are misleading because they create the false impression that there are no serious risks associated with the use of Lindane Shampoo or Lindane Lotion according to directions.

77. As the FDA pointed out in its Warning Letter, promotional material for Morton Grove's products is misleading if it "omits critical information reflected in the Public Health Advisory and in the PI for Lindane Shampoo regarding the risks of the drug associated with normal use (which includes seizures and death)." Such materials create "the misleading suggestion . . . that serious adverse reactions will not occur when Lindane Shampoo is used as directed."

78. As of 2003, at least 20% of the adverse events with serious outcomes (hospitalization, disability, or death) reported in the FDA's Adverse Event Reporting System as related to use of lindane pesticidal treatments resulted from uses according to directions.

79. As of 2003, the FDA reported that there were at least 14 deaths associated with use of pesticidal treatments containing lindane. The FDA further noted that five of these – in

other words, 35.7% – occurred when the product was used in accordance with the label instructions.

80. The FDA has also acknowledged that its own Adverse Event Reporting System provides insufficient data to quantify the risks associated with the "proper" use (or misuse) of lindane pesticidal treatments. In its 2003 Public Health Advisory, the FDA stated that "[r]ates of adverse events cannot be calculated from [the FDA's Adverse Event Reporting S]ystem and underreporting is presumed, especially for older products like Lindane Lotion and Shampoo."

81. The FDA's mandated "black box" public health warnings for Lindane Shampoo and Lindane Lotion warns that "[s]eizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application according to directions."

82. The FDA's 2003 Public Health Advisory states: "Most serious adverse events reported in association with Lindane products have been due to misuse. However, there have been rare case reports of serious reactions with apparently normal use. These reports highlight the need to emphasize the potential toxicity of Lindane in the product labels and educate healthcare providers and patients about the risks and how to minimize them . . . ."

83. The statements set forth in paragraphs 48-49, 51, and 63, as well as the context in which each statement appears, omit discussion or identification of the serious adverse events that can result from use of lindane pesticidal treatments even in accordance with directions.

84. Thus, the statements set forth in paragraphs 48-49, 51, and 63 falsely or misleadingly suggest that there is no risk of serious adverse events when Lindane Lotion or Lindane Shampoo are used as directed, or that the only serious adverse events associated with usage of Lindane Lotion or Lindane Shampoo arise as a result of misuse.

Morton Grove's Misleading Suggestion That The Risk Of Side Effects Is Insignificant

85. The statements set forth in paragraphs 48-49, 51, 63, 68-70, and 73-74 are misleading because they create the false impression that the risks associated with the use of Lindane Shampoo or Lindane Lotion are so rare that they should be disregarded when deciding whether to use or prescribe the products.

86. In its 2003 Public Health Advisory, the FDA warned that "[a]mong the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia."

87. The FDA has recognized that those considering prescribing or using lindane pesticidal treatments should be aware of and consider the risks and potential serious side effects. One purpose of the FDA's mandated "black box" public health warning for Lindane Shampoo and Lindane Lotion is "to better inform both healthcare professionals and patients regarding the potential risks associated with the use and misuse of Lindane" because "[g]iven the possible risks associated with the use of Lindane, healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug events."

88. As the FDA pointed out in its Warning Letter, a promotional piece that "fail[s] to include **any** risk information regarding treatment with Lindane Shampoo" is misleading.

89. Specifically, Morton Grove's promotional materials are misleading if they "omit and/or minimize the most serious and important risk information associated with the use of Lindane Shampoo, particularly in pediatric patients" and "convey . . . little about the magnitude and nature of the risks associated with the drug."

90. The letters, enclosures, and web pages in which the statements set forth in paragraphs 48-49, 51, and 63 appear omit discussion or identification of the risks and potential serious side effects of the use of lindane pesticidal treatments, such as seizures and death, while affirmatively stating that lindane pesticidal treatments are safe.

91. Thus, the statements set forth in paragraphs 48-49, 51, 63, 68-70, and 73-74 falsely or misleadingly suggest that there are few risks associated with the use of Lindane Lotion or Lindane Shampoo.

Morton Grove's Misleading Suggestions That Lindane Pesticidal Treatments Are Safe For All Patients

92. The statements set forth in paragraphs 48-49, 51, 63, 68-70, and 73-74 are misleading because they create the false impression that for all patients, the risk of side effects or adverse events as a result of using Lindane Lotion and Lindane Shampoo is insignificant.

93. In particular, the statements set forth in paragraphs 68-70 and 73-74 are misleading because they create the false impression that Lindane Lotion and Lindane Shampoo are safe to be used on children and pregnant mothers.

94. The FDA's mandated "black box" public health warning for Lindane Shampoo and Lindane Lotion warns that the pesticidal treatments should be used "with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity."

95. The FDA's labeling information for Lindane Shampoo and Lindane Lotion states: "Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Shampoo [or Lindane Lotion] is applied. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver."

96. The FDA's 2003 Public Health Advisory states: "Lindane is contraindicated for use in neonates and should be used with extreme caution in children and in individuals weighing less than 50 kg (110 lbs). Among adverse event reports in which the outcome was serious (resulted in hospitalization, disability or death), the very young and the elderly appeared to be more susceptible to Lindane's adverse effects and had worse outcomes. Animal studies have demonstrated that younger animals are more susceptible to the neurologic side effects seen with Lindane use. In addition, smaller children have a larger body surface to volume ratio that may result in proportionately larger risk of systemic exposure. For this reason, Lindane has long been contraindicated for use in neonates. It is not known whether the developing nervous system of children also increases their susceptibility to neurologic toxicity."

97. The FDA's 2003 Talk Paper, issued in conjunction with its Public Health Advisory and mandated "black box" warning, explains that the FDA's warnings about the use of lindane pesticidal treatments in pediatric patients were "based on reports to the FDA's voluntary reporting system which described approximately one half of reported adverse events occurred in pediatric patients."

98. The FDA's labeling guidelines also warn that "[i]f the person applying Lindane Shampoo [or Lindane Lotion] could be pregnant, contact with Lindane Shampoo [or Lindane Lotion] should be avoided as much as possible."

99. As the FDA pointed out in its Warning Letter, Morton Grove's promotional materials are misleading if "they make prominent claims of effectiveness for Lindane Shampoo for the treatment of head lice in children but omit and/or minimize important risk information from the body of the pieces, including crucial facts about potentially fatal risks associated with the use of Lindane Shampoo in this vulnerable population," because "[t]his omission of risk

information is completely at odds with the current labeling for Lindane Shampoo, which describe a drug associated with potentially fatal risks."

100. The FDA further explained that Morton Grove promotional materials that "targeted pediatric patients who are at particular risk with respect to [lindane pesticidal treatments]" were "misleading in that they omit and/or minimize the most serious and important risk information associated with the use of Lindane Shampoo, particularly in pediatric patients."

101. The FDA further identified as misleading a web page that carried a "principal message[] . . . that Lindane Shampoo offers safe and effective treatment for head lice in all children, a message plainly at odds with labeling" because "Lindane Shampoo should be used with caution in children because its use has been associated with seizures and death, and because of this risk it is a second line treatment."

102. The FDA further identified as misleading promotional material that stated only that "some products may not be suitable" for use by patients who are pregnant or breastfeeding because it "fail[ed] to convey that a patient should not use Lindane Shampoo while breastfeeding as it is present in human breast milk and may cause toxicity if ingested from breast milk."

103. The letters, enclosures, and web pages in which the statements set forth in paragraphs 48-49, 51, 63, 68-70, and 73-74 appear omit discussion of the patients for whom the use of lindane pesticidal treatments is contraindicated, such as infants and those with uncontrolled seizure disorders, and those patients for whom lindane pesticidal treatments must be used "with caution," such as the elderly and those weighing less than 110 pounds – in other words, most children. At the same time, these letters, enclosures, and web pages make prominent claims about the safety and/or efficacy of lindane pesticidal treatments.

104. Thus, the statements set forth in paragraphs 48-49, 51, 63, 68-70, and 73-74 falsely or misleadingly suggest that Lindane Shampoo and Lindane Lotion are safe for all patients and/or that there are no risk concerns when Lindane Shampoo or Lindane Lotion is suggested for use on certain patient populations, particularly children and pregnant mothers.

105. In particular, the statements set forth in paragraphs 68-70 and 73-74 falsely or misleadingly suggest that Lindane Lotion and Lindane Shampoo are safe to be used on children and/or that Lindane Lotion and Lindane Shampoo do not cause serious side effects in children.

106. Moreover, the statements set forth in paragraphs 68-70 falsely or misleadingly suggest that Lindane Lotion and Lindane Shampoo are safe to be used on pregnant mothers and/or that Lindane Lotion and Lindane Shampoo do not cause serious side effects in pregnant mothers and/or their unborn fetuses.

Morton Grove's Attacks on NPA

107. NPA is a small non-profit organization that, since 1983, has attempted to educate the public about safe and effective methods for managing and treating head lice.

108. NPA's mission has included warning the public about the dangers of the chemical lindane and its use in lice and scabies pesticidal treatments. NPA has also warned the public of the dangers associated with other pesticidal lice and scabies treatments.

109. NPA sells the LiceMeister® Comb as a non-chemical, medical device that can be used to screen, detect, and manually remove lice and nits. NPA also maintains non-profit 501(c)(3) status.

110. Morton Grove's aggressive tactics for marketing and advertising its Lindane Shampoo and Lindane Lotion have included, among other things, filing lawsuits against NPA

and the Ecology Center, Inc., another non-profit organization that has educated the public about the dangers of the chemical lindane and its use as a pharmaceutical product.

111. In the enclosure identified above in paragraph 50, Morton Grove makes the following statement: "[S]tatements against the use of lindane medication in favor of nit combs must be closely scrutinized as these statements have been aggressively advanced by the National Pediculosis Association (NPA), a special interest group of non-healthcare professionals that directly profits from the sale of nit comb products." (Exs. B-F at MGP001064.)

112. Morton Grove also maligns NPA on the websites www.lindane.com and www.lindanetruth.com.

113. Both those websites state that the "[m]isleading [c]laim" that "[m]anual removal of lice and nits with special combs or other mechanical means is the best treatment for infestation and prevention of recurrence" is "often made by the National Pediculosis Association (NPA), which holds itself out as a nonprofit health organization but actually makes its money by marketing a competitive medical device to lindane shampoo without employing a single licensed healthcare professional." (Ex. G.)

114. The statements identified in paragraphs 111 and 113 falsely and misleadingly suggest that NPA is the only organization advocating the use of nit combs to manually remove lice and nits – in other words, that only an organization that "makes its money" marketing a nit comb would recommend its use to manage head lice, and that disinterested parties do not recommend combing.

115. The statements identified in paragraphs 111 and 113 falsely and misleadingly imply that NPA is the only organization urging a non-chemical approach to the treatment of head lice.

116. The statements identified in paragraphs 111 and 113 falsely and misleadingly imply that NPA educates the public about the dangers of lindane pesticidal treatments in order to increase its profits.

117. The statements identified in paragraphs 111 and 113 falsely and misleadingly imply that NPA is a sham non-profit organization.

118. The statements identified in paragraphs 111 and 113 falsely and misleadingly imply that the NPA's LiceMeister® Comb is ineffective in helping individuals manage head lice.

Morton Grove's Statements Have Harmed NPA

119. As a result of the Morton Grove statements identified in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, NPA's reputation and goodwill has been damaged.

120. Specifically, Morton Grove's plans for marketing its lindane products have included responding directly to the information related to the chemical lindane or lindane pesticidal treatments that can be found on NPA's websites, www.headlice.org and www.lindane.org, or in NPA publications. By promoting Lindane Shampoo and Lindane Lotion through the false or misleading statements identified in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, Morton Grove unfairly discredits NPA and hinders its efforts to educate the public about the dangers of lindane pesticidal treatments. Thus, as a result of these Morton Grove statements, NPA's 25-year reputation for educating the public about safe and effective options for managing and treating head lice has been irreparably tarnished.

121. NPA will continue to experience this irreparable harm so long as Morton Grove makes false or misleading statements like those identified in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113. Thus, the irreparable harm to NPA is continuing and warrants injunctive and other equitable relief.

122. Moreover, as a result of the Morton Grove statements identified in paragraphs 111 and 113, consumer perception of NPA's LiceMeister® Comb as an effective tool for managing head lice has been irreparably damaged.

123. NPA denies that the LiceMeister® Comb competes with Lindane Shampoo or Lindane Lotion, and hence that it competes with Morton Grove for market share. However, to the extent that this Court determines that Morton Grove and NPA are competitors, Morton Grove's false and misleading advertising, as set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, negatively affects sales of NPA's LiceMeister® Comb by increasing the market share of Lindane Shampoo or Lindane Lotion at the expense of the market share of the LiceMeister® Comb.

124. NPA will continue to experience this irreparable harm so long as Morton Grove makes false and misleading statements like those identified in paragraphs 111 and 113. The statement identified in paragraph 113 remains on www.lindane.com and www.lindanetruth.com. Thus, the irreparable harm to NPA is continuing and warrants injunctive and other equitable relief.

Morton Grove Acted Intentionally to Promote Its Products

125. Morton Grove's campaigns for advertising and promoting Lindane Lotion and Lindane Shampoo reflect a sophisticated and carefully designed effort to downplay the risks associated with uses of these products.

126. Morton Grove made the statements identified in paragraphs 48-49, 51, 63, 68-70, and 73-74 with the full intention of hiding the ball and misleading the public as to the dangers of using Lindane Lotion and Lindane Shampoo, and continued to make misleading promotional and

marketing claims even after the FDA Warning Letter pointed out the misleading nature of its claims. Thus, Morton Grove made these statements willfully and maliciously.

127. Morton Grove's attacks on NPA, as set forth in paragraphs 111 and 113, are part of its overall campaign to silence those who are working to educate the public about the dangers of the chemical lindane and lindane pesticidal treatments.

128. Morton Grove made the statements identified in paragraphs 111 and 113 willfully and maliciously.

COUNT I
VIOLATION OF THE ILLINOIS DECEPTIVE TRADE PRACTICES ACT
(815 ILCS 510/2)

129. NPA repeats and realleges as if fully set forth herein the allegations set forth in paragraphs 1 through 128 of this Counterclaim.

130. Morton Grove published and communicated the statements, set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, to third persons.

131. Morton Grove published and communicated the statements, set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, in the context of commercial advertising or promotion.

132. The statements set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113 contain false or misleading assertions of fact about Morton Grove's product(s), about NPA as a non-profit corporation, or about NPA's LiceMeister® Comb.

133. The statements set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113 violate several sections of the Illinois Deceptive Trade Practices Act, 815 ILCS 510/2, including section (a)(5) and (a)(12).

134. As a result of the statements set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, NPA has suffered the harm identified in paragraphs 119 through 124.

135. As a result of the statements set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, NPA has suffered injury entitling it to injunctive and other equitable relief.

COUNT II
VIOLATION OF THE LANHAM ACT (15 U.S.C. § 1125(a))

(In the alternative, should the Court hold that Morton Grove and NPA are competitors, which NPA expressly denies):

136. NPA's primary position is that it is not a competitor to Morton Grove. To the extent, however, that this Court concludes that NPA and Morton Grove are competitors for purposes of Morton Grove's standing to sue NPA under the Lanham Act, NPA asserts a Lanham Act claim and pleads as follows:

137. NPA repeats and re-alleges the allegations set forth in paragraphs 1 through 136 of this Counterclaim.

138. Morton Grove's statements, set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, were made in connection with commercial advertising or promotion of Morton Grove's products, Lindane Shampoo or Lindane Lotion.

139. Morton Grove's statements, set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, contain false and misleading descriptions and representations of fact about Lindane Shampoo, Lindane Lotion, NPA as a non-profit corporation, or NPA's product, the LiceMeister® Comb.

140. Morton Grove's statements, set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, contain assertions of fact about Lindane Shampoo, Lindane Lotion, NPA as a non-profit corporation, or NPA's product, the LiceMeister® Comb, that are misleading in context.

141. Morton Grove's statements, set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, have deceived and have a tendency to deceive a substantial portion of their target audience.

142. Morton Grove's statements, set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, are material to consumers' purchasing decisions regarding Lindane Shampoo, Lindane Lotion, or NPA's LiceMeister® Comb.

143. Morton Grove has caused the statements set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113 to enter interstate commerce.

144. Morton Grove's statements, set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, have caused and are continuing to cause injury to NPA, including in the form of lost goodwill.

145. Morton Grove's statements, set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113, have caused and are continuing to cause irreparable injury to NPA and injury that is not compensable through money damages.

WHEREFORE, Counterclaim Plaintiff, NATIONAL PEDICULOSIS ASSOCIATION, INC., requests this Honorable Court grant it the following relief:

(a) An order permanently enjoining Morton Grove from the further dissemination of the false and/or misleading statements identified in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113;

(b) An order requiring Morton Grove to publish corrective advertising and to contact and provide correct information to the specific individuals to whom the false and/or misleading statements identified in paragraphs 48-49, 51, 68-70, 73-74, and 111 were directed, as well as to any other individuals to whom it specifically directed similarly false and/or misleading statements;

(c) NPA's court costs and attorneys' fees; and

(d) Such other and further relief as the Court deems equitable and just.

Dated: May 6, 2008

Respectfully Submitted,

THE NATIONAL PEDICULOSIS ASSOCIATION, INC.

By: s/ Amanda S. Amert
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CERTIFICATE OF SERVICE

I, Amanda S. Amert, hereby certify that on May 6, 2008, I caused copies of the foregoing **Defendant The National Pediculosis Association, Inc.'s Answer And Affirmative And Other Defenses, and Counterclaim Against Morton Grove Pharmaceuticals, Inc., and accompanying exhibits,** to be served upon the following via electronic filing through the CM/ECF system:

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